EXHIBIT 11

United States Department of Justice

Civil Division

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COMMUNICATION MADE PURSUANT TO FEDERAL RULE OF EVIDENCE 408

September 30, 1999

BY FACSIMILE AND FIRST CLASS MAIL

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Chicago, Illinois 60601-1692

Re: United States ex rel. [Relator] v.
[Abbott Labs] [FILED UNDER SEAL]

Dear Mr. Reidy:

The purpose of this letter is to notify your client Abbott Laboratories ("Abbott") that a qui tam has been filed naming it as a defendant in a False Claims Act matter. This qui tam matter is still subject to a sealing order, and you may not disclose its existence beyond your client. In addition to this notification, our purpose is also to inform you and your client of our perspective of the legal and factual elements of the case as the government determines whether to proceed against Abbott under the False Claims Act and/or common law theories.

In the qui tam complaint, which is over two hundred pages in length (exclusive of exhibits), the relator alleges that Abbott caused the Medicare and the state Medicaid programs to pay excessive reimbursement for infusion and oncology drugs by inflating the drugs' Average Wholesale Prices ("AWP"), Wholesale Acquisition Costs ("WAC"), and Direct Prices ("DP"). The states and the federal government use these prices as benchmarks in establishing provider reimbursement for hundreds of thousands of National Drug Codes. The relator alleges that Abbott is aware of this reliance and, in turn, manipulated the AWPs, WACs, and DPs so as to increase the Medicare and Medicaid reimbursement paid to Abbott's customers. These customers, healthcare providers, are paid through claims presented to Medicaid and Medicare which are allegedly false because these claims knowingly overstated several

times over both the provider acquisition cost and the wholesaler acquisition cost for the drugs. The complaint alleges that Abbott is culpable for the submission and payment of these false claims because of the high degree of control that it exercises over the amount of reimbursement paid to the providers.

A. Legally Enforceable Or "Truthful" Claims May Still Be Rendered False By A Fraudulent Course of Conduct

The provider claims at issue in the qui tam are neither facially "truthful" nor legally enforceable. Even if a court disagreed, however, the courts have repeatedly looked beyond the face of such claims to the nature of the conduct underlying the submission of the claims. In past False Claims Act litigation, the government has successfully relied on the proposition that a claim that may be truthful on its face can be rendered false if it was submitted pursuant to a fraudulent course of conduct.

In United States v. Incorporated Village of Island Park, 888 F. Supp. 419 (E.D. N.Y. 1995), the district court held that

> the provisions of the False Claims Act are to be read broadly and reach beyond "claims" which might be legally enforced, to all fraudulent attempts to cause the Government to pay out sums of money; thus the statute is violated not only by the person who makes a false statement or false record to get the government to pay a claim, but also by one who engages in fraudulent course of conduct that causes government to pay a claim for money. (Emphasis added).

Island Park, 888 F. Supp. at 439, citing United States v. McLeod, 721 F. 2d 282, 284 (9th Cir. 1983)(payments by government for timber sale proceeds were legally enforceable claims but not enforceable by defendant who no longer owned land)(quoting United States v. Niefert-White Co., 390 U.S. 228, 233, 88 S. Ct. 959, 962 (1968).

Island Park is not a "rogue" decision but rather a well-reasoned one that includes a lengthy precedential and legislative backdrop for the court's holding.[1] The Island Park court makes clear that "the legislative history indicates that the FCA was intended to cover each and every claim submitted . . . by means

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[1] The expansive language of the Niefert-White opinion was recently cited with approval in United States v. Carpentieri, 1998 WL 749042, *4 (October 26, 1998 S.D.N.Y.)(Sand, J.) quoting United States v. General Dynamics, 19 F.3d 770,773 (2d Cir. 1994)("refus[ing] to accept a rigid, restrictive reading" of FCA).

of false statements, or other corrupt or fraudulent conduct, or in violation of any statute or applicable regulation." S. Rep. No. 345 at 9, reprinted in 1986 U.S. Code Cong. and Admin. News, 5266, 5274. Bid-rigging schemes, such as that described in United States ex rel. Marcus v. Hess, 317 U.S. 537 (1943), are indicative of claims that technically may not be false but that were derived from "a fraudulent course of conduct." The "truthful" claims become false because of the fraudulent course of conduct used to trick the government into paying them. See also United States v. CFW Construction Co., 649 F. Supp. 616, 618 (D.S.C. 1986)(in bid rigging cases the proscribed harm does not stop with the execution of the contract but extends to each intermediate step along the path to payment by the government), appeal dismissed, 819 F. 2d 1139 (4th Cir. 1987).

The Island Park court followed this analysis when it held the following:

> "[w]hen claims for payment on those mortgages were submitted by the innocent mortgagees, the fraudulent course of conduct pursuant to which the mortgages were approved emerge in `full vigor' and become part of those claims, which therefore constitute false claims within the meaning of the False Claims Act."

Island Park, supra, at 440.

Other holdings that similarly deal with otherwise legally enforceable claims include United States ex rel. Sanders v. East Alabama Healthcare Authority, 953 F. Supp. 1404 (M.D. Ala. 1996)(no requirement that government prove that services underlying alleged false Medicare and Medicaid claims were "unnecessary, not rendered") citing Peterson v. Weinberger, 508 F. 2d 45, 52 (5th Cir. 1975); United States ex rel. LaValley v. First National Bank of Boston, 707 F. Supp. 1351, 1352 (D. Mass. 1988)(lender's claim upon government loan guarantee was not fraudulent but false statement in loan application was); and United States v. Ehrlich, 643 F. 2d 634 (9th Cir.) cert. denied 454 U.S. 940 (1981).

The progeny of the Niefert-White case do not require a showing that the defendant violated a specific statute or regulation. Even so, the allegedly false and misleading price information disseminated by Abbott potentially violates the Food and Drug Administration's ("FDA") primary labeling provision contained in the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C.A. § 301 et seq. We believe that the FDA, which has direct regulatory authority over your client and its products, will conclude that Abbott's price representations (directly to the Medicaid programs, First DataBank, Medi-Span and/or the Red Book) may be false and/or misleading within the meaning of section 502 of the FDCA.

B. Abbott's AWPs May Be False and Fraudulent Even If It Argues That The AWPs Represent a "Reasonable Interpretation" Of An Ambiguous Regulation or Statute

After the fact assertions by drug manufacturers that their AWPs are set under "reasonable" criteria in the face of "ambiguous" guidance from applicable regulations and statute cannot provide a dispositive defense to the qui tam allegations. The Ninth Circuit Court of Appeals' recent decision in United States ex rel. Oliver v. Parsons Company, et al., 1999 WL 503843 (9th Cir. (Cal.))(July 19, 1999), gives a cogent analysis of why this defense argument fails. In Oliver, the panel held that the district court erred in finding that the "'falsity' element under the Act was not met because Parsons demonstrated that it made a reasonable interpretation of an ambiguous accounting standard, citing Hagood v. Sonoma County Water Agency . . . ". Oliver, 1999 WL 503843, at *3. The Ninth Circuit stated that "Hagood does not stand for the proposition that a 'reasonable interpretation' of a regulation precludes falsity." Id. The Ninth Circuit concluded, rather, that it is "Parsons' compliance with these regulations, as interpreted by this court, that determines whether" the claims were false. Id.

The purported "reasonableness" of a drug manufacturer's interpretations of Average Wholesale Price and Wholesale Acquisition Cost cannot alone preclude a finding of falsity. The Oliver court explicitly approved of the Department of Justice's reading of the law in footnote 2 where it stated

> the Government correctly points out the potential problem created by embracing a 'reasonable interpretation' exception to the 'falsity' of a claim. A defendant could submit a claim, knowing it is false or at least with reckless disregard as to falsity, thus meeting the intent element, but nevertheless avoid liability by successfully arguing that its claim reflected a 'reasonable interpretation' of the requirements. Id. at *5.

We have extensive evidence of deceptive manufacturer marketing tactics designed to shift excessive government drug reimbursement dollars from payors to providers. In one Abbott document, dated January 1996, the Abbott employee outlines an ongoing Abbott scheme to set the AWP of Calcijex at 125% of the "single case price" because the Medicare program only reimburses Abbott's customers for "80% of the published AWP." This scheme which was "not something new and [] is not a change in policy" resulted in Abbott customers being reimbursed for at least 100%

of their acquisition cost for the drug rather than Medicare's stated policy of paying 80%. The Abbott employee states that Abbott inflates the AWPs for "other HPD products" by "120% of list." This evidence — that Abbott knowingly circumvents government Medicare policy — contradicts any assertion that Abbott employs "reasonable interpretations" of the applicable Medicaid and Medicare regulations and statutes.

B. False Statements To Government Contractors Or Other Third Parties May Also Provide the Predicate For A False Claims Act Violation

In addition to the allegedly false and misleading price representations made directly to the state Medicaid programs by your client, the evidence shows that Abbott submitted price information to First DataBank, a contractor to the state governments, that was allegedly intended to give a false impression of the true wholesale and direct prices of the drugs at issue here. These allegedly false statements may form the predicate of a False Claims Act violation even though the communications were not directly between your client and the government. Moreover, the case law in the Eleventh Circuit extends the reach of the False Claims Act to false statements made to third parties who are not government contractors. Under the latter circumstance, false statements to Medi-Span and Red Book must also be taken into consideration.[2]

In United States ex rel. Luther v. Consolidated Industries, et al., 720 F. Supp. 919 (N.D. Ala. 1989)(false claims submitted by subcontractor to government contractor), the court led its analysis with the following: "[a] false claim is actionable although the claims or false statements were made to a party other than the Government, if the payment would ultimately result in a loss to the United States." Luther, 720 F. Supp. at 921. The Luther court cited a number of other supporting opinions involving false statements made to government contractors and other entities not directly in a contractual relationship with the government. See, e.g., United States v. Lagerbusch, 361 F. 2d 449 (3rd Cir. 1966)(defendant's false representations were made to private employer which operated government installation under terms whereby government reimbursed employer for all operating costs), United States v. Douglas, 626 F. Supp. 621, 626-27 (E.D. Va. 1985)(film makers potentially liable for false report submitted to Navy by Navy pilot used by filmmakers to

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[2] In the January 1996 Abbott memorandum referenced above, the Abbott employee notes that Abbott sends the inflated AWPs to Medi-Span so that the Medicare Intermediaries, who "get their pricing from the published AWP's of the three reporting agencies," will receive the false and misleading information.

organize stunts even though filmmakers took no part in making report), and Murray & Sorenson, Inc. v. United States, 207 F. 2d 119 (1st Cir. 1953). As the Luther court summed up, "even though the false claims in this case were presented to Teledyne, and not the government directly, a claim was submitted 'upon or against the government' under the False Claims Act." Id.

We find additional authority in the Fourth Circuit Court of Appeals' recent decision in Harrison v. Westinghouse Savannah River Company, 1999 WL 308587 (4th Cir. (S.C.))(May 17, 1999)(defendant allegedly made false statements in order to induce government into offering subcontract to third party), as significant evidence of the likelihood that the courts will view Fujisawa as culpable for the provider claims submitted to Medicaid and Medicare. The decision makes clear that the holding of United States v. Niefert-White — that the False Claims Act is "intended to reach all types of fraud, without qualification, that might result in financial loss to the Government" — is a sound cornerstone of False Claims Act case law. Harrison, supra, at *9, quoting, United States v. Niefert-White, 390 U.S. 228, 232 (1968).

In the decision, the Harrison court makes clear that False Claims Act liability extends to cover any source of false information sent to the government whether or not that source is the "recipient or beneficiary of the fraudulently induced contract." Id. at *14. This liability attaches not just in the case of contracts and subcontracts but any time there is " . . . fraud surrounding the efforts to obtain the contract or benefit status, or the payments thereunder." Id. at *9. This is so whether or not the claims submitted were otherwise "truthful." Id. In fact, the Harrison court's opinion is closely aligned with the reasoning set forth in our letter to you, dated April 26, 1999.

Nowhere in the opinion does the Harrison court restrict the definition of "falsity" to statements that violate a statute or regulation. Nor does the court require a falsified certification. Rather the court takes the common sense approach of analyzing — through its four prong test -- whether or not the allegedly false statement is true. Id. at *9.

For example, in January 1995, Abbott sent a memorandum to First DataBank by facsimile that purports to give Abbott's "trade" and "wholesale" prices for Dextrose 50% Injection 2000ML. Abbott reported a wholesale price of $238.74. This price far exceeds the actual wholesale price of Dextrose when sold through an infusion wholesaler such as Florida Infusion or Oncology Therapeutics Network. Similarly, on September 23, 1998, Abbott informed First DataBank by electronic mail that the "Direct" price of Vancomycin HCL was $612.90 per package of ten while the "WHLS" price was $380.00 per package of ten. These prices far

outstrip the actual direct and wholesale prices of these products that were commonly purchased through the so-called distributor channels. For example, the Ultracare wholesale catalog lists the same Vancomycin NDC at $7.41 per unit and $370.59 for a package of 50. Additional inflated "Wholesale" prices were provided for Dextrose 5% Injection 150 ML, Sodium Chloride 0.9% Injection 10 ML, and Sodium Chloride 0.9% Injection 150 ML on November 24, 1998.

In April and May 1995, Abbott provided inflated "wholesale" prices for Amikacin Sulfate and Vancomycin HCL. Abbott staff notes from March 1997 confirm that Abbott employees consider WAC and "wholesale" to be synonymous so there is little doubt that Abbott understood that it was representing WAC prices as the prices at which it was selling its products to wholesalers. Even as Abbott provided First DataBank in 1998 with Direct Prices that were hundreds of dollars higher than WAC prices for products such as Acyclovir, Abbott staff appear to have chalked up the discrepancies to "contract savings" that applied only to WAC pricing.

These allegedly false or misleading statements — whether made directly to the states or transmitted through First DataBank, Medi-Span or the Red Book — would very likely fall within the Eleventh Circuit definition of materiality. In United States v. Diaz, 690 F. 2d 1352, 1357 (11th Cir. 1982), the Eleventh Circuit held that an allegedly false statement is material if "[it] had a natural tendency to influence, or be capable of affecting or influencing a government function." Moreover, the government does not have to show

> actual reliance on the false statements. A statement can be material even if it is ignored or never read by the agency receiving the misstatement. False statements must simply have the capacity to impair or pervert the functioning of a government agency.

Id.

Based on the current evidence, Abbott's conduct appears to have directly contributed to the costly perversion of the functioning of both the Medicare and Medicaid reimbursement systems.

C. Defendants' Assertion of "Government Knowledge" Is Undermined By Repeated Industry Lobbying Regarding AWP And Actual Drug Cost

During the course of our investigation, we have become aware of the assertion that the "government" had knowledge that AWP is not indicative of providers' actual acquisition cost for

pharmaceuticals. Even taking this at face value, this assertion is only an affirmative defense to the allegation that your client acted "knowingly" within the meaning of the False Claims Act. Assertions of government knowledge will be undermined by (1) contrary assertions within the industry that AWP is a representation of actual cost and (2) false and misleading price representations made by Abbott directly to state Medicaid agencies.

Specifically, we have credible evidence that at least one defendant — acting in concert with an "independent" patient group — represented to congressional staffers this past October that AWP is the actual measure of cost to providers for a host of oncology drugs. These representations were not limited to this defendant's products but, in fact, were made about the brand name and generic versions of many chemotherapy drugs without reference to specific manufacturers. These facts will undermine the government knowledge defense.

Moreover, throughout 1996, one defendant used a consultant, characterized as an "independent" health care provider group, which attempted to influence Medicare Carrier medical directors on important reimbursement issues.[3/] This evidence further demonstrates the tactics used by the industry to discourage reforms in the drug reimbursement system. Ironically, one letter-writing campaign involved the defendant's effort to discredit a major product by another defendant. The consultant intended to discredit this other company without stampeding HCFA into "implementing new reimbursement methodologies" that would result in acquisition cost reimbursement in the Medicare and Medicaid programs."[4/] The consultant was also concerned about the government discovering that it was actually acting on behalf of the first defendant.

[3/] The purported provider interest group upon whose letterhead the Medicare correspondence was sent had the same mailing address and telephone number as that of the consultants hired by the defendant.

[4/] The evidence will also reflect that HCFA — rather than acquiescing to AWP-based reimbursement — took steps to shift Medicare reimbursement to an actual acquisition cost basis (see 42 C.F.R. Part 405.517) in 1992. HCFA was thwarted on procedural grounds by measures sponsored by the American Society of Clinical Oncologists — a constituency that reaps tremendous financial benefit from the continuation of AWP-based reimbursement. The state Medicaid programs have consistently taken discounts off of AWP in recognition that it overstates costs by 10-20%.

As to the second counter to the "government knowledge" defense, in June 1993, Abbott provided false and misleading wholesale price information about Vancomycin HCL in response to Texas Medicaid's request for accurate, certified wholesaler and distributor price information. For example, Abbott listed Vancomycin HCL, 1 gram for $49.42 per unit and $494.20 per case of 10. Ultracare listed the same product with a unit price of $7.41 and offered a case of 50 units for $370.59. In January 1993, Abbott provided similarly misleading wholesale price information about Dextrose 5% injectable solution. These documents demonstrate that states did seek accurate price reporting for reimbursement purposes.

We suspect that this evidence is only the tip of the iceberg. Our view is that the "government knowledge" defense can be effectively countered on summary judgment by evidence that the industry has undermined the impact of HCFA's and the Office of Inspector General's price/cost research by systematically giving important government officials misleading information regarding AWP's relationship to actual cost.

Conclusion

At this time, we are not persuaded that either (1) the purported lack of false statements directly to the government, (2) the "government knowledge defense" or (3) the "truthful" claims defense can establish -- as a matter of law -- that neither the federal nor the state governments have a claim for which relief can be granted.

Thus far, the evidence supports the allegation that your client was engaged in a course of conduct designed specifically to get provider claims paid in amounts far exceeding what the providers — particularly those purchasing from wholesalers — paid to acquire their products. Your client was never compelled by the government to create dramatic reimbursement "spreads" for its products. Moreover, your client has the unilateral power to eliminate these "spreads" overnight.[5]

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[5] We have compiled evidence showing that other large drug companies — operating within the same system — not only resist the temptation to set initial wide spreads or increase spreads over time but actually reduce AWP's when their customers' actual acquisition costs go down. The preliminary evidence shows that the normal "spread" is approximately 16.66%. This figure is well within the range of state efforts to discount AWP for reimbursement purposes. Several manufacturers that are also defendants in this qui tam have dozens of products for which they have set spreads of exactly 16.66% where the spread reflects actual wholesale prices to providers.

Government payors should not have to change their systems of drug reimbursement just to police reimbursement abuses involving what appears to be less than 1% of the tens of thousands of drugs on their formularies. Our view is in accord with the Eleventh Circuit Court of Appeals in United States v. Calhoon, 97 F. 3d 518, 528 (11th Cir. 1996), when it stated that the Medicare reimbursement system is not to be reduced to "a cat and mouse game" where the overwhelmed government is required to police the honesty of providers seeking to maximize profits. The Eleventh Circuit acknowledged that the government has neither the resources nor the obligation to audit the entire Medicare system. We think this observation is no less applicable to the Medicaid system.

Feel free to contact us to discuss the evidence (documents or potential witness interviews) or case law that you consider relevant to the government's intervention decision. We look forward to hearing from you.

Sincerely,

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